Doc Code: AP.PRE.REQ

PTO/SB/33 (07-05) Approved for use through xx/xx/200x. OMB 0651-00xx
U.S. Patent and Trademark Office, U.S. DEPARTMENT OF COMMERCE
d to a collection of information unless it displays a valid OMB control number.

PRE-APPEAL BRIEF REQUEST FOR REVIEW		Docket Number (Optional)	
		P22020.00	
I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to "Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)]	Application N	lumber	Filed
	10/646,254		08-22-2003
on	First Named Inventor		
Signature	Tom Breton		
Art Unit		Examiner	
Typed or printed name	3731		Sonnett, Kathleen
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.			
This request is being filed with a notice of appeal.			
The review is requested for the reason(s) stated on the attached sheet(s).  Note: No more than five (5) pages may be provided.			
I am the	2/1/2		
applicant/inventor.	<u> </u>		
	Signature		
assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)	<u>*************************************</u>	Katrina A. Witschen Typed or printed name	
X attorney or agent of record. 59, 862	763-505-8418		
X attorney or agent of record. 59,862	Acres Continues	Telephone number	
attorney or agent acting under 37 CFR 1.34.	<u> </u>		
Registration number if acting under 37 CFR 1.34			Date
NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.			
*Total of forms are submitted.			

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Breton, et. al Examiner: Kathleen Sonnett

Serial No.: 10/646,254 Group Art Unit: 3731

Filing Date: 8-22-2003 Docket No.: P22020.00

Title: EVERSION APPARATUS AND METHODS

**MS After Final** 

Commissioner for Patents PO Box 1450

Alexandria, VA 22313-1450

## PRE-APPEAL BRIEF REQUEST FOR REVIEW--ARGUMENTS

Applicants request review of the final rejection of claims 1-14 in the above-identified application. These claims, as they appear in the Listing of the Claims on pages 2-4 of the Amendment and Response filed April 17, 2007 were rejected in the Final Office Action mailed September 24, 2007.

Claims 1, 2, 4-9 and 11-14 were rejected under 35 U.S.C. § 102(b) as being anticipated by Kato (U.S. Patent No. 6,979,337). The Examiner asserts "Kato discloses the invention substantially as claimed including an everting member with a loop-shaped portion (col. 4, lines 24-30) that is coupled to a handle (grip portions [32a] and [32b] or [7] as the handle), wherein the everting member comprises a flexible member having two ends (col. 4, lines 25-35)." In support of the 35 U.S.C. §102(b) rejection of Claim 1 the Examiner alleges that "the device with multiple piercing members is not positively recited in claim 1" and "[t]he language 'for preparing a conduit for anastomosis in a human patient using a device with multiple piercing members' is a recitation of the intended use of the claimed invention. If the prior art structure is capable of performing the intended us and has all of the positively recited structure, then it meets the claim" (Final Office Action p.2). This rejection is respectfully traversed.

The Applicants respectfully submit that Kato does not disclose each and every element of Claim 1 and the claims dependent therefrom. Applicants disclose in Claim 1, "a surgical eversion apparatus for preparing a conduit for anastomosis in a human patient

Serial No. 10/646,254

Filing Date: August 22, 2003

Title: EVERSION APPARATUS AND METHODS

Dkt.: P22020.00

using a device with multiple piercing members, said eversion apparatus comprising..." The language of claim 1, "using a device with multiple piercing members" is part of the claim preamble and as such must be read in the context of the entire claim. "The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim."" M.P.E.P. 2111.02 II citing Corning Glass Works, 868 F.2d at 1257, 9 USPQ2d at 1966. Therefore, contrary to the Examiner's assertion, the language in Claim 1 is not merely a statement of intended use or purpose. Rather, Claim 1 discloses structure which is not disclosed in Kato.

Kato does not disclose a device with multiple piercing members nor does the Examiner point to where in Kato such structure could be found. According to M.P.E.P. 2111.02 I, "[a]ny terminology in the preamble that limits the structure of the claimed invention must be treated as a claim limitation." See, e.g., *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257, 9 USPQ2d 1962, 1966 (Fed. Cir. 1989). Since Kato discloses no such terminology, Kato fails to anticipate Claim 1 and the claims dependent therefrom.

Regarding independent Claim 8, Applicants disclose "a vessel eversion system for preparing a vessel for anastomosis in a human patient, said vessel eversion system comprising: a vessel support device...". Kato does not disclose a vessel support device. The Examiner alleges "Kato discloses a vessel support device that the vessel can be flipped over by using the evasion apparatus and wherein the vessel is coupled to and extends from the distal end of the support device." (Final Office Action pp. 3-4). The Examiner also alleges "no structure is given in claim 8 to differentiate the ring (60) of Kato from the claimed support device. It is further noted that the ring provides support for the folded over conduit." (Final Office Action p. 2). However, Kato describes only a "clip ring 60" which is "supported by, for example, being pinched between tweezers (not shown)." See e.g. Kato, Col. 6 lines 36-37; Col. 12 lines 65-67. Accordingly, the clip

Dkt.: P22020.00

Serial No. 10/646,254

Filing Date: August 22, 2003

Title: EVERSION APPARATUS AND METHODS

ring 60 itself requires support and as such is not of itself a support device. Thus, Kato does not disclose the clip ring as being a support device.

Therefore, it is respectfully submitted that the pending claims are novel and structurally distinguishable from the cited art. Thus, claims 1, 2, 4-9 and 11-14 are patentable over Kato. Hence, withdrawal of the 35 U.S.C. §102(b) rejection of claims 1, 2, 4-9 and 11-14 is proper and respectfully requested.

The Examiner rejected claims 3 and 10 under 35 U.S.C. §103(a) as being unpatentable over Kato (U.S. Patent No. 6,979,337). In particular, the Examiner asserts that Kato discloses the invention substantially as claimed but fails to disclose the embodiment wherein both ends of the flexible loop are slidable with respect to the handle (Final Office Action p. 4). This rejection is respectfully traversed.

The Examiner asserts for the first time that it would have been obvious to have both ends of the loop slidably attached to the handle "because such a modification would have been considered a mere design consideration." (Final Office Action p. 4).

Applicants respectfully submit however that, "[t]he mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims on appeal is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason for the worker in the art, without the benefit of appellant's specification, to make the necessary changes in the reference device." *See* M.P.E.P. 2144.04 VI. C. citing *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984).

The Examiner alleges that having both ends of the loop being slidably mounted to the handle solves no particular problem, serves no particular purpose nor provides any additional benefit over having only one end slidably mounted. (Final Office Action p. 4). As Applicants originally argued in response to this contention, obviousness is not established for lack of a statement indicating that an invention solves some existing problem. (April 17<sup>th</sup>, 2007 Response and Amendment p.6). Therefore, Applicants respectfully submit that *prima facie* obviousness has not been established. As discussed above, the cited art does not disclose or suggest all the limitations of claims 3 and 10.

Page 4

Serial No. 10/646,254

Filing Date: August 22, 2003

Title: EVERSION APPARATUS AND METHODS

Dkt.: P22020.00

Withdrawal of the 35 U.S.C. §103(a) rejection of claims 3 and 10 is therefore respectfully requested.

Applicants respectfully submit that the claims are in condition for allowance, and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicants' attorney at (763) 505-8418 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 13-2546.

Date: March 20, 2008

Respectfully submitted,

Katrina A. Witschen

Reg. No. 59,862

Patent Counsel

MEDTRONIC, INC.

710 Medtronic Parkway

Minneapolis, MN 55432

Tel. 763-505-8418

Fax. 763-505-8436

Customer No. 27581